K062355

DEC 27 2006

CONFIDENTIAL

XI. 510(k) Summary

Submitter: Mr. Eugenio Miceli, QA Manager, Micerium SpA, Via Marconi, 83, 16030 Avegno (GE), Italy. Phone: 39 0185 7885 880.

I. Classification Name and Number: Cement, dental (EMA 872.3275).

II. Common/Usual Name: Dental cement for post and core, direct and indirect restoration.

III. Proprietary Name: ENA CEM.

IV. Registration No.: K062355

V. "ISO 4049:2000 Dentistry – Polymer – Based Filling, Restorative and Luting materials".

VI. Description of the Device: The ENA CEM is a luting material available in a flowable consistency (Ena Cem) and also in a high viscous version (Ena Cem HF) that is available in different colours. Both can be used for cementing prosthesis appliances made in laboratory to the tooth. They can be used also for post-cementation. Ena Cem HF can also be used for core build-up and as a liner. The accessories and try-in materials contact tissue for less than 1 hour and therefore are exempt from 510(k) requirements and are described only generally.

VII. Labels and Labeling: Draft labels of the ENA CEM and instructions for use are provided.

VIII. Substantial Equivalence: The ENA CEM system is substantially equivalent to some other dual composite cements currently on the market used by dentist for luting prosthesis made with several types of dental materials as well as for post and core. A list of these is provided.

The composition of these dental composite cements is very similar: resin matrix made of polymerizable monomers, (glass) fillers, and all of them are dual cure materials. The packaging is similar because all products are packaged in self mixing syringes. Regarding indications, all products can be used for luting of almost all dental appliances. Physical characteristics are similar although one version of Ena Cem, Ena Cem HF, has better physical properties that allow also the core build up and a better performance regarding wear resistance.

VIII.1 Risks to Health

Potential adverse affects and complications common to composite materials include:

- Allergy to one of the ingredients
- Incorrect / insufficient filling of the root canal
- Incorrect / incomplete curing of erroneous polymerisation

Cytotoxicity tests appears in appendix V.1

IX. Indications for Use. EnaCem is a dual curing radiopaque fluorescent luting composite, available in several dentine colours, for cementation of posts, ceramic and composite inlay, onlay veneers and crowns. It can be used also for core build-up and as a liner.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2006

Mr. Eugenio Miceli
Quality Assurance Manager
Micerium S.p.A.
Via Marconi 83
16030 Avengo
ITALY

Re: K062355
Trade/Device Name: ENA CEM
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: December 19, 2006
Received: December 22, 2006

Dear Mr. Miceli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Linda A Murphy, MD for Chiu Lin, PhD

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062355

Device Name: ENA CEM

Indications For Use: EnaCem is a dual curing radiopaque fluorescent luting composite, available in several dentine colours, for cementation of posts, ceramic and composite inlay, onlay veneers and crowns. It can be used also for core build-up and as a liner.

Prescription Use ___X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Angela Blackwell for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K062355